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August 27, 1999

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Neurontin (Gabapentin) Tablets, 600 mg and 800 mg, (NDA-20-882), by Parke Davis, have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications. That list, referred to as the "Orange Book", contains all FDA-approved drug products. The Orange Book currently lists Neurontin Tablets, 600 mg and 800 mg, in the Prescription Drug Product List section. A listing in this section of the Orange Book indicates that the specific drug product is the subject of an approved application. However, based on a survey of the marketplace, Neurontin Tablets, 600 mg and 800 mg, are not available for sale to the consumer.

Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The

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regulations also provide that the agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved [21 CFR 314.161(a)(1)].

As stated, Parke-Davis' Neurontin Tablets, 600 mg and 800 mg, are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product, it is requested that the FDA determine whether Parke-Davis' decision not to market Neurontin Tablets, 600 mg and 800 mg, was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided if so requested.

E. Certification

The undersigned certifies that, to its best knowledge and belief, this petition includes all information and views on which the petition relies, and that includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock (RWP)

Robert W. Pollock
Vice President

RWP/db

FAK9239

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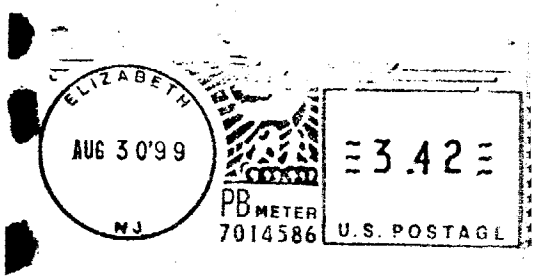

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